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November 23, 2015

#### **VIA ECF & FEDEX**

The Honorable Douglas E. Arpert, U.S.M.J. United States District Court Clarkson S. Fisher Building & U.S. Courthouse 402 East State Street Trenton, NJ 08608

Re: Sucampo AG, et al. v. Dr. Reddy's Laboratories, Inc., et al.

Civil Action No. 14-7114 (MAS)(DEA)

Dear Judge Arpert:

This firm, together with Paul Hastings LLP and Patterson Belknap Webb & Tyler LLP, represents Plaintiffs in the above-captioned matter. We write in opposition to the November 13, 2015 letter motion (D.I. 43) sent to Your Honor by the Dr. Reddy's defendants ("DRL") regarding Plaintiffs Local Patent Rule 4.2(a) exchange of "Preliminary Claim Constructions." DRL's motion should be denied because it ignores this Court's claim construction procedures and improperly requests that the Court order Plaintiffs to redefine their claim constructions under a flawed interpretation of case law related to "plain meaning" constructions.

The Local Patent Rules set out a defined three-step procedure for presenting to the Court a Joint Claim Construction and Prehearing Statement that identifies the parties' proposed terms for claim construction. See L. Pat. R. 4.2(a)-(c). Local Patent Rule 4.2(a) provides that the parties exchange a list of their preliminary proposed constructions, and Rule 4.2(c) then requires identification of all intrinsic and extrinsic evidence that each party intends to reply upon to oppose any party's proposed constructions. Finally, Rule 4.2(d) states that the parties shall meet and confer for the purpose of narrowing the issues and finalizing preparation of a Joint Claim Construction and Prehearing Statement. See L. Pat. R. 4.2(d). Significantly, the Local Patent Rules do not require a party to redefine their proposed claim constructions at the request of another party prior to submission of Rule 4.2(c) evidence, or at any other time.

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As an initial matter, DRL's request for substantive findings from Your Honor regarding Plantiffs' proposed claim constructions is flawed because it ignores Judge Shipp's province regarding such issues.

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#### DRL's Motion Should Be Denied As Improper And Flawed

Pursuant to the Court's Pretrial Scheduling Order (D.I. 29), the parties have already exchanged their preliminary proposed constructions for the disputed claim terms and their respective identification of pertinent intrinsic and extrinsic evidence. Plaintiffs disclosed that, to the extent such terms are subject to *Markman* proceedings, those terms should be given their "plain meaning" based on the evidence recited in Plaintiffs' disclosures. On October 15, the parties exchanged their respective identification of evidence intended to rebut each other's proposed constructions as required by Local Patent Rule 4.2(c).

DRL alleges that Plaintiffs' preliminary proposed constructions are in violation of this Court's rules. However, Plaintiffs have satisfied the disclosure requirements under Local Patent Rule 4.2 because "plain meaning" is an adequate and proper claim construction position under both the Local Patent Rules and Federal Circuit law, which this Court has routinely accepted and adopted. DRL offers no contrary case law or analysis of the Local Patent Rules to support its bald assertions that "plain meaning" constructions are "[c]ontrary to the letter and purpose of the Rules." *See* DRL's November 13 Letter at 1.

DRL relies on a scheduling order from another court in support of its argument that Plaintiffs' Local Patent Rule 4.2(a) disclosures are improper. *See* DRL's November 13 Letter at 1 (citing Judge Sue Robinson's Patent Case Scheduling Order (D. Del.)). The cited scheduling order does not control here and there is no evidence that it stands for the proposition that "plain and ordinary meaning" constructions are improper. Such a rule would be inconsistent with Federal Circuit precedent that has held that "plain and ordinary meaning" is an appropriate and sufficient construction for a claim term that does not require any further articulation. *See, e.g.*, *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1206-1207 (Fed. Cir. 2010) (affirming decision adopting plaintiff's construction of "plain and ordinary meaning," rejecting defendant's competing construction that did not comport with the "plain and ordinary meaning" in view of the intrinsic evidence, and finding no error where the jury was instructed, without further articulation, "to give the rest of the words in the claim their plain and ordinary meaning").<sup>2</sup>

Parties may submit "plain and ordinary meaning" as their proposed construction in their Local Patent Rule 4.2(a) disclosures. *See, e.g.*, Revised Joint Claim Construction and Prehearing Statement, *Depomed, Inc., v. Actavis Elizabeth LLC*, C.A. No. 12-1358 (JAP)(TJB), D.I. 188 (D.N.J. May 14, 2013) at B-36, B-39, B-42, B-46 (listing "[p]lain and ordinary meaning; does not require construction" as the proposed construction for multiple terms); Joint Claim Construction and Prehearing Statement, *Millipore Corp. v. W.L. Gore Associates, Inc.*, C.A. No. 11-1453 (ES), D.I. 32 (D.N.J. Oct. 19, 2011) at 2 (listing "no construction necessary" as a

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DRL also fails to note that the District Court for the District of Delaware has applied "plain and ordinary meaning" as a sufficient and complete claim construction. *See*, *e.g.*, "Order Construing The Terms of U.S. Pat. Nos. 5,780,676 & 5,962,731," C.A. No. 11-901-GMS, D.I. 101 (D. Del., July 2, 2013) at 3 (construing term "useful to treat skin cancer" as having "its plain and ordinary meaning" – with no further articulation – and rejecting the opposing party's construction upon finding that the opposing construction "complicates and improperly narrows the meaning of the term by importing limitations from extrinsic evidence").

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proposed construction); Supplemental Joint Claim Construction and Prehearing Statement, *Astrazeneca Pharm. LP v. Handa Pharm., LLC*, C.A. No. 08-3773 (JAP)(TJB), D.I. 89 (D.N.J. Dec. 11, 2009) at 23 (listing "plain and ordinary meaning; no construction required" as a proposed construction). Moreover, this Court has routinely accepted and adopted "plain meaning" as a complete construction. For example, this Court has previously construed all of the following terms as having their "plain and ordinary meaning" – as terms that were "well understood" or "clear" to a person of ordinary skill in the art – without requiring any further articulation or sub-construction:

- "dispersed in a gastric retained dosage form"
- "administration"
- "wherein the dosage form provides administration of at least 80 wt% of the gabapentin to be delivered over a period of about 5–12 hours"
- "wherein the administering achieves a reduced incidence of side effects to the central nervous system, relative to a non-gastric retained dosage form"
- "said dosage form being one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water"
- "said matrix being one that swells in an unrestricted manner along both such axes upon imbibition of water"
- "swells in a dimensionally unrestrained manner by imbibing water"
- "gas generating agent"

See Depomed, Inc., v. Actavis Elizabeth LLC, C.A. No. 12-1358 (JAP)(TJB), 2014 WL 316702, at \*6-11 (D.N.J. Jan. 28, 2014). Indeed, it is illogical for DRL to state that "plain meaning" may not be offered as a construction, but that Plaintiffs should instead redefine their claim constructions using other words.

Even in attempting to distinguish cases such as *Finjan* and *Depomed*, DRL admits that "claim scope should not be improperly expanded or contracted beyond the plain meaning when that meaning is clear to a person of skill in the art." *See* DRL's November 13 Letter at 3; *see also id.* at 4 ("[L]ike *Depomed*, the *Finjan* case stands for the proposition that a court should not construe a claim term to depart from its plain meaning to a person of ordinary skill in the art unless there is a good reason to do so."). However, DRL also insists that "plain meaning" is not itself a construction, despite acknowledging that the Federal Circuit affirmed a construction of "plain and ordinary meaning" for the claim term "addressed to a client." DRL's November 13 Letter at 3; *Finjan*, 626 F.3d at 1206-07. DRL's arguments focus on a single term at issue in *Depomed*, while ignoring at least *eight* other claim terms for which the Court adopted a construction of "plain and ordinary meaning," without requiring any further definition. *See Depomed*, 2014 WL 316702, at \*6-11. And as for the single term that DRL focuses on, the Court did not redefine "plain meaning" in other terminology, but illustrated why the opposing

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party's construction was inconsistent with "plain meaning." *Id.* at \*9-10. The key finding in both the *Finjan* and *Depomed* cases is that the opposing party's construction was *not* the "plain meaning" as understood by a skilled artisan in view of the pertinent evidence. *See id.*; *Finjan*, 626 F.3d at 1206-07.

Finding no legal support for its erroneous proposition that "plain meaning' is not a construction standing alone," DRL instead lists vague grievances that do not withstand scrutiny. For example, DRL alleges that it is "left to guess whether the 'plain meaning' of the disputed terms to Plaintiffs is the same as their 'plain meaning' to DRL." *See* DRL's November 13 Letter at 1, 4. DRL's hypothetical is irrelevant here because DRL does not, and has never, asserted that its proposed constructions are equivalent to the plain and ordinary meaning. Nor are Plaintiffs "hiding the ball," as DRL asserts. *See id.* at 1. Plaintiffs have already explained to DRL during a lengthy meet and confer concerning each claim term at issue that DRL's proposed constructions do not comport with the "plain meaning" as understood by a person of ordinary skill in the art in view of the pertinent evidence, including the evidence cited in Plaintiffs' Local Patent Rule 4.2(a)-(b) disclosures.

DRL also says it expects Plaintiffs to "explain how their 'plain meanings' differ from DRL's proposed construction" (*id.* at 2), but fails to mention that *DRL* has refused to explain what its proposed constructions mean. *See* Plaintiffs' October 20 Letter attached hereto as Exhibit A; DRL's October 22 Letter attached hereto as Exhibit B. Plaintiffs cannot begin to consider exactly how DRL's unsupported constructions using non-claim term language differ in scope from the "plain meaning" to a person of ordinary skill in the art, when DRL either refuses to or is unable to tell Plaintiffs what its proposed constructions mean. What is clear, however, and what Plaintiffs have told DRL, is that DRL's constructions – which apparently are *not* the plain meaning – do not comport with the pertinent intrinsic and extrinsic evidence to be considered under *Phillips* and other applicable Federal Circuit law. That is the parties' "actual dispute" at this time, which is more appropriately addressed by meeting and conferring as required by Local Patent Rule 4.2(d) in order to prepare the Joint Claim Construction and Prehearing Statement for the Court.

Relying on the *O2 Micro* case, DRL suggests that "'plain and ordinary meaning' may be inadequate" where it "does not resolve the parties' dispute." DRL's November 13 Letter at 3 (quoting *O2 Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351 (Fed. Cir. 2008)). In the *O2 Micro* case, the opposing parties asserted "plain meaning" constructions of a claim term, but had an unresolved dispute regarding the plain meaning that the Federal Circuit found should have been resolved by the court, not a jury. *See id.* at 1361. The facts of *O2 Micro* are not relevant here and the case does not stand for DRL's proposition that "plain meaning" can *never* resolve a claim construction dispute. To the contrary, courts regularly resolve exactly this type of dispute by adopting a "plain meaning" construction (and nothing more) where, as here, the opposing party's constructions are not justified in view of the law and pertinent evidence. For example, the Federal Circuit in *Finjan* distinguished *O2 Micro*, finding that a "plain meaning" construction *can* resolve a claim construction dispute where the district court rejects an opposing party's non-plain meaning construction as unjustified in view of the pertinent intrinsic evidence. *See Finjan*, 626 F.3d at 1206-07 (citing *O2 Micro*, 521 F.3d at 1360). Likewise, this Court in *Depomed* resolved multiple claim construction disputes by adopting "plain and ordinary

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meaning" without further definition and rejecting the opposing party's constructions for lacking support in the pertinent evidence. *See Depomed*, 2014 WL 316702, at \*6-11. Plaintiffs anticipate any disputes over the proper constructions and the application of "plain and ordinary meaning" will be fully addressed by the parties in their *Markman* briefs and resolved by the Court in its *Markman* Order, as is the usual case for *Markman* proceedings in this Court.

DRL's other cited case law does not support its untenable position that "plain meaning" is not a construction. Although DRL reads *Thorner* to include a further description of the disputed term beyond "plain and ordinary meaning," that reading is not plain from *Thorner* and it cannot be read to require a further description in every case. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362 (Fed. Cir. 2012). Nothing in the *Phillips* case or the cases which followed it suggest that "plain meaning" is merely a "guidepost" or that "determining the ordinary and customary meaning" requires further articulation or sub-construction. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-1314 (Fed. Cir. 2005) (*en banc*). The Federal Circuit has instead made clear that "plain meaning" can be a construction.

\* \* \*

Accordingly, Plaintiffs respectfully ask Your Honor to deny DRL's motion. Further, Plaintiffs respectfully request that Your Honor revisit the adjourned deadlines so that the parties may move forward with claim construction proceedings in accordance with the Local Patent Rules and as previously agreed upon by the parties.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

William C. Baton

William C. Baton

cc: All Counsel (via e-mail)

# **EXHIBIT A**

### PAUL HASTINGS

1 (212) 318-6815 yousefmian@paulhastings.com

October 20, 2015

#### **VIA E-MAIL**

Louis H. Weinstein, Esq. BUDD LARNER, P.C. 150 John F. Kennedy Parkway Short Hills, NJ 07078

Re: Sucampo AG, et al. v. Dr. Reddy's Laboratories, Ltd., et al.

C.A. No. 14-cv-07114

Dear Lou:

We understand that Judge Arpert contacted both DRL and Plaintiffs via telephone to inquire about the status of the dispute addressed in DRL's October 8 letter and Plaintiffs' October 9 letter to the Court regarding the parties' proposed claim constructions.

The parties have now provided their October 15 statements of rebuttal evidence under L. Pat. R. 4.2(c). It is our understanding that (1) any previous dispute does not require further consideration by Judge Arpert and (2) the parties will continue to meet and confer as needed in advance of preparing the Joint Claim Construction and Prehearing Statement, which is due on November 2. Any differences regarding the proper claim construction of the asserted patent claims can sufficiently be addressed in the ordinary course of claim construction exchanges and briefing, as provided by the Local Patent Rules and the Scheduling Order.

If DRL disagrees with Plaintiffs' assessment, we request that DRL explain whether it still maintains that Plaintiffs' "plain meaning" constructions are insufficient or are contrary to the requirements of the Local Patent Rules, and, if so, why. For example, while DRL did not cite to any decision on claim construction to support its assertion, Plaintiffs provided DRL with authority demonstrating that this Court has held that a disputed term's "plain and ordinary meaning" may be proposed and adopted by the Court as an appropriate claim construction. *See*, *e.g.*, *Depomed*, *Inc.* v. *Actavis Elizabeth LLC*, C.A. No. 12-1358 JAP, 2014 WL 316702, at \*6-11 (D.N.J. Jan. 28, 2014) (holding that "[disputed term's] plain and ordinary meaning shall apply" to multiple disputed terms). If DRL believes that the circumstances of this case are different from those of the *Depomed* case, please explain.

Moreover, we understand that DRL's claim construction inquiries are focused on whether certain non-claim term phrases are "included" within the "plain meaning" constructions Plaintiffs have proposed. We have already informed DRL that, to the extent Plaintiffs understand DRL's proposed constructions, none of them comport with the plain meaning as

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understood by a person of ordinary skill in the art in view of the pertinent intrinsic and extrinsic evidence. *See* Plaintiffs' October 7, 2015 E-Mail to DRL. Further, Plaintiffs have stated that for them to address what is and is not included, DRL must explain what it means by the various non-claim terms in its proposed constructions, which differ from the claim language at issue and do not appear to be related to the intrinsic evidence. Specifically, if DRL still maintains that Judge Arpert needs to address the parties' October 8 and October 9 letters regarding claim construction, please provide DRL's understanding of the meaning of the claim terms below from DRL's proposed claim constructions. We are hopeful that, if DRL can state with specificity what it means, the parties can avoid unnecessarily burdening the Court.

Claim Term	Non-Claim Terms From DRL's Proposed Constructions
"a patient"	"a human or animal patient"
"wherein the ratio of the bicyclic to mono-cyclic tautomer is"	"ratio of the bicyclic to mono-cyclic tautomer in CDCl <sub>3</sub> "
"dosage unit"	"an amount of halogenated PG analog to be administered"
"irritable bowel syndrome"	"any type of irritable bowel syndrome"
	"constipation predominate- irritable bowel syndrome"
	"diarrhea predominate- irritable bowel syndrome"
"treating irritable bowel syndrome"	"any symptom of any type of irritable bowel syndrome"
	"constipation in a patient with constipation predominate-irritable bowel syndrome"
	"constipation predominate-irritable bowel syndrome"
"systemic administration"	"administration directly into the systemic circulation"

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"abdominal discomfort"	"any abdominal pain or discomfort"
	"heartburn"
	"nausea"
	"emesis"
	"anorexia"
	"epigastric pain"
	"abdominal bloating"
	"chronic abdominal pain"
	"an uncomfortable abdominal sensation not described as pain"
	"abnormal bowel movement such as constipation and diarrhea"
	"and the like"
"treating abdominal discomfort associated with irritable bowel syndrome"	"any abdominal discomfort associated with any type of irritable bowel syndrome"
	"any type of irritable bowel syndrome"
	"constipation in a patient with constipation predominate- irritable bowel syndrome"
	"constipation predominate-irritable bowel syndrome"

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If necessary, we propose that the parties meet and confer and request a written response to the above questions in advance. Plaintiffs are available on Tuesday, October 27.

Very truly yours,

Yousef M. Mian

for PAUL HASTINGS LLP

cc: Chad Peterman, Esq.

# **EXHIBIT B**

#### **BUDD LARNER**

A PROFESSIONAL CORPORATION COUNSELLORS AT LAW

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October 22, 2015

#### VIA E-MAIL

Yousef Mian, Esq. Paul Hastings, LLP 75 East 55<sup>th</sup> Street New York, NY 10022

Re: Sucampo AG, et al. v. Dr. Reddy's Laboratories, Inc., et al.

Civil Action No. 14-7114 (MAS)(DEA)

Dear Yousef:

We have your letter of October 20. We disagree with Plaintiffs' statement that "any previous dispute [concerning the sufficiency of Plaintiffs' disclosure of "plain meaning" as their proposed construction of disputed terms] does not require further consideration by Judge Arpert." We further disagree that "DRL's claim construction inquiries are focused on whether certain non-claim term phrases are 'included' within the 'plain meaning' constructions Plaintiffs have proposed."

In our previous letters to you and to Judge Arpert, as well as in our recent meet and confer, we told you repeatedly that "plain meaning" is not a claim construction, and that we are entitled to an explanation of what "plain meaning" Plaintiffs ascribe to each of the disputed claim terms. Without this information, which you have still refused to provide, DRL cannot determine whether there is actually a dispute between the parties with respect to the construction of any of the disputed claim terms, or identify relevant rebuttal evidence should a dispute actually exist. You now seek to turn this simple inquiry on its head by demanding to know how DRL defines certain alleged "non-claim terms" in DRL's proposed construction of these terms. We decline your invitation to participate in this Alice-in-Wonderland exercise.

The Local Patent Rules require *you* to identify *your* position with respect to the construction of disputed claim terms. Your naked assertion of "plain meaning" does not satisfy this requirement. In this regard, we note that you have now dropped your reliance on *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362 (Fed. Cir. 2012). This is understandable because, consistent with what we told you during our October 13 meet and confer, *Thorner* actually supports DRL's position. Significantly, in *Thorner*, the party proposing "plain

NEW YORK CHERRY HILL SHORT HILLS PHILADELPHIA

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meaning" did not conceal its position, as plaintiffs do here. Rather, the party asserting "plain meaning" explicitly argued that "the plain and ordinary meaning includes affixing an item to either an exterior or an interior surface." *Id.* at 1367. The opposing party argued in response that "attached" was limited to only an exterior surface. The Federal Circuit held that the term should be given its plain and ordinary meaning, but did not hold that "plain and ordinary meaning" was in itself the proper construction. To the contrary, the Federal Circuit held "that the term 'attached to said pad' should be given its plain and ordinary meaning which encompasses either internal or external attachment." *Id.* at 1368.

Your reliance on "plain meaning" as a claim construction also ignores the Federal Circuit's decision in O2 Micro Int'l Ltd. v. Beyond Innovation Tech Co., 521 F.3d 1351, 1361 (Fed. Cir. 2008). In O2 Micro, "the parties agreed that the term 'only if' has a common meaning, but then proceeded to dispute the scope of that claim term . . . . " Because the parties disagreed about the common meaning of "only if," the Federal Circuit chastised the District Court for refusing to construe this term before sending the case to the jury. The Court explained, "[a] determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." Id. The Court's reasoning in O2 Micro applies with equal force here. Plaintiffs' reliance on "plain meaning" as a proposed construction does not allow DRL or the Court to determine if there is a dispute concerning claim construction, let alone permit DRL to designate evidence to rebut Plaintiffs' undisclosed constructions. See also Phillips v. AWH Corp., 415 F. 3d 1303, 1314 (Fed. Cir. 2005) (en banc) (in many cases giving rise to litigation, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art.")

Plaintiffs' reliance on *Depomed, Inc. v. Actavis Elizabeth LLC*, 2014 U.S. Dist. LEXIS 10190 (D.N.J. Jan. 28, 2014) is also misplaced. *Depomed* did not hold that "plain meaning" is in itself an adequate construction of a disputed claim term. Rather, the case stands for the proposition that claim scope should not be improperly expanded or contracted when the meaning of a claim term is clear to a person of skill in the art. For example, the parties in *Depomed* disputed the meaning of "dispersed in a single polymer matrix." But while Defendants argued that "the plain and ordinary meaning should apply," they explained "that under the plain and ordinary meaning of this term there is 'one and only one drug-containing matrix in the claimed dosage form." *Depomed*, 2014 U.S. Dist. Lexis 10190 at \*27. In contrast here, Plaintiffs have refused to disclose the alleged "plain meaning" of *any* disputed claim term.

The foregoing cases affirm our argument that Plaintiffs are required to tell us what their position is with respect to the alleged "plain meaning" of each disputed claim term. We emphatically reject your attempt to turn *your* obligation under this Rule into DRL's obligation by demanding an explanation of DRL's interpretation of certain alleged "non-claim terms" in DRL's proposed constructions.

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Once you have met your obligation to disclose your position concerning the alleged "plain meaning" of all disputed claim terms, we are happy to work with you to resolve any disputes concerning claim scope in order to streamline the Court's *Markman* review.

Very truly yours,

s/ Louis H. Weinstein
Louis H. Weinstein

LHW/mit 1065862